

### ***Remarks***

#### ***I. Support for Amendments***

By the foregoing amendments, claims 12 and 118 are sought to be amended. The amendment to claim 12 is sought to revise the dependency of this claim. The amendment to claim 118 is to correct a grammatical error.

New claims 119-146 are sought to be added. New claim 119 is supported by the originally filed claims and specification including, *inter alia*, original claims 12 and 18. New claims 120-123 and 126 are supported by the originally filed claims and specification including, *inter alia*, page 49, lines 17-18 of the present specification (published as WO 2004/084939). New claim 124 is supported by the originally filed claims and specification including, *inter alia*, original claims 115-117. New claim 125 is supported by the originally filed claims and specification including, *inter alia*, page 47, lines 13-18 of the present specification. New claim 127 is supported by the originally filed claims and specification including, *inter alia*, original claim 24. New claim 128 is supported by the originally filed claims and specification including, *inter alia*, original claim 30. New claim 129 is supported by the originally filed claims and specification including, *inter alia*, original claim 35. New claims 130-135 are supported by the originally filed claims and specification including, *inter alia*, original claim 2. New claim 136 is supported by the originally filed claims and specification including, *inter alia*, original claim 118. New claim 137 is supported by the originally filed claims and specification including, *inter alia*, original claim 30. New claim 138 is supported by the originally filed claims and specification including, *inter alia*, original claim 33. New claim 139 is supported by the originally filed claims and specification including, *inter*

*alia*, original claim 35. New claim 140 is supported by the originally filed claims and specification including, *inter alia*, original claim 42. New claims 141-143 are supported by the originally filed claims and specification including, *inter alia*, page 25, lines 27-30; page 27, lines 3-9; and page 49, lines 17-24 of the present specification. New claims 144-146 are supported by the originally filed claims and specification including, *inter alia*, original claims 12 and 17.

Applicants respectfully submit that these amendments place the application in condition for allowance and do not raise any new issue requiring further search or examination. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

## ***II. Status of the Claims***

By the foregoing amendments, claims 3, 5, 13, 16, 20, 22, 23, 26, 28, 29, 31, 32, 34, 36, 37-41, 43-47, 50-93, 100, 101 and 105-107 were cancelled previously and claims 18, 49, 94-99, 102-104, 108-112 and 114 have been cancelled herewith without prejudice to or disclaimer of the subject matter therein. Claims 4, 6, 7, 9-11, 49, 94-96, 98, 99, 102-104, 108-110, 112, 113 and 114 have been withdrawn by the Examiner. Claims 12 and 118 have been amended. New claims 119-146 have been added. As discussed above, these amendments add no new matter to the present application. Upon entry of these amendments, claims 1-2, 4, 6-12, 14, 15, 17, 19, 21, 24, 25, 27, 30, 33, 35, 42, 48,

113 and 115-146 are pending in the application, with claim 1 being the sole independent claim.

### ***III. Withdrawn Claims***

Claims 4, 6, 7, 9-11, 49, 94-96, 98, 99, 102-104, 108-110, 112, 113 and 114 have been withdrawn by the Examiner. Claims 49, 94-96, 98, 99, 102, 103, 104, 108-110, 112 and 114 have been cancelled without prejudice to or disclaimer of the subject matter therein. Pending claims 4, 6, 7, 9-11 and 113 were withdrawn by the Examiner as not reading on an elected species. Applicants would like to remind the Examiner that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. Accordingly, Applicants believe that the currently pending claims are in condition for allowance and request the rejoinder and examination of withdrawn claims 4, 6, 7, 9-11 and 113.

### ***IV. Obviousness-Type Double Patenting***

At page 3, claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42 and 48 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1, 10, 14-16, 41, 48 and 55 of copending application 10/563,944 ("the 944 application").

Applicants would like to draw the Examiner's attention to MPEP § 1490.V.D. which states that:

If two (or more) pending applications are filed, in *each* of which a rejection of one claimed invention over the other on the ground of provisional obvious-type double patenting (ODP) is proper, the ODP rejection will be made in each application. If the ODP rejection is the only rejection remaining in the earlier filed application of the two pending applications, (but the later-filed application is rejectable on other grounds), the examiner should then withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

The priority date of the '944 reference application used in making this obviousness-type double patenting rejection is July 10, 2003, i.e., about four months *after* the priority date of the present application. Applicants believe that the amendments and arguments presented herein will place the present application in condition for allowance except for the obviousness-type double patenting rejection. Thus, Applicants request the Examiner to hold this rejection in abeyance until the arguments and amendments herewith have been considered, and to withdraw this rejection upon allowance of the present claims in accordance with MPEP § 1490.V.D.

#### ***IV. Rejection under 35 U.S.C. § 112***

At pages 3-6 of the Office Action, the Examiner has rejected claims 97 and 111 under the first paragraph of 35 U.S.C. § 112, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully disagree with the Examiner's comments and traverse this rejection.

As an initial matter, Applicants respectfully disagree with the statements at page 5 of the Office Action, wherein the Examiner alleges that "[w]hile the specification does

contain statements regarding the use of the VLPs as an HIV vaccine, there is no indication that an HIV-1 specific immune response has been generated . . . ." Applicants respectfully contend that this statement by the Examiner is overly broad and incorrect. In fact, the present specification discloses an HIV-1 specific immune response can be generated by the present invention:

The invention further provides vaccination methods for preventing and/or attenuating diseases or conditions in animals. In one embodiment, the invention provides vaccines for the prevention of infectious diseases in a wide range of animal species, particularly mammalian species such as human, mouse, or monkey, wherein the antigenic determinant is from the relevant virus infecting said species or is an antigenic determinant relevant to the particular animal model of the disease. Vaccines can be designed to treat infections of viral etiology such as HIV.

It is well known that homologous prime-boost vaccination strategies with proteins or viruses are most often unsuccessful. Preexisting antibodies, upon re-encountering the antigen, are thought to interfere with the induction of a memory response. To our surprise, the RNA-phage derived VLPs, in particular the VLP derived from Q $\beta$ , do very efficiently induce a memory CD8<sup>+</sup> T cell response in a homologous prime-boost vaccination scheme. In contrast, live vaccinia virus immunizations are very ineffective for the induction of a primary CD8<sup>+</sup> T cell response and homologous boosting with vaccinia does hardly lead to an expansion of memory CD8<sup>+</sup> T cells.

WO 2004/084939 at page 73, lines 6-14 (corresponding to US 2006/0210588 at ¶¶ 0268-0269).

Nonetheless, solely to advance prosecution and not in acquiescence to the Examiner's rejection, Applicants have cancelled claims 97 and 111; thus, this rejection is rendered moot.

***V. Objections***

At page 6 of the Office Action, the Examiner has objected to claims 12, 14, 15, 17-19 and 115-118 as being dependent upon a rejected base claim. Applicants believe that the amendments and remarks presented herein have addressed all rejections and have placed this application in condition for allowance. Thus, Applicants respectfully request the Examiner to withdraw this objection.

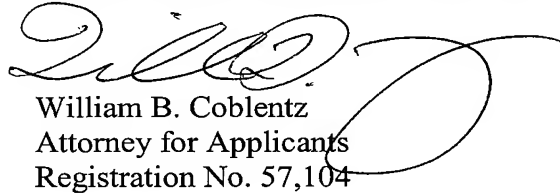
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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